MENA's Fake Pharma Conundrum

Dempsey, Adam; Karasik, Theodore

Veröffentlichungsversion / Published Version
Zeitschriftenartikel / journal article

OPINION | MENA's Fake Pharma Conundrum

indrastra.com/2017/06/OPINION-MEAN-s-Fake-Pharma-Conundrum-003-06-2017-0002.html

By Adam Dempsey and Theodore Karasik

Not so long ago *Médecins Sans Frontières* (MSF) made a shocking discovery in the Democratic Republic of Congo. Hundreds of patients had unwittingly taken Haloperidol instead of Diazepam to treat malaria-induced seizures, meningitis, and other illnesses. The side effects caused by this powerful antipsychotic were horrific. Many victims suffered facial cramps, contorted upper bodies and other equally bizarre symptoms.

It's the type of backyard horror story that's inspired the governments of *the Middle East and North Africa (MENA)* to regularly remind citizens of the dangers of counterfeit medicines. Warnings are often attached to media coverage of seizures, as well as updates on state-led initiatives to combat a trade worth an estimated USD 200 billion a year. And with good reason. While the scourge of fake pharmaceuticals affects all parts of the world, the problem is growing in the MENA region, where healthcare can be in short supply but high demand.

Changing Demographics, Changing Priorities

According to the **United Nations Development Program**, the MENA region's population is expected to increase from approximately 360 million in 2011 to almost 500 million by 2030. However, rather than being driven by a consistently high birthrate, the region's demographic changes will be more attributable to life expectancy, which the **World Bank estimates** increased from 46 to 72 years between 1960 and 2014. As a result, MENA states will increasingly face the type of health problems associated with the aging populations of Germany, Japan, and other advanced high-income countries.

MENA's growing diabetes burden certainly warrants close attention. The **International Diabetes Federation** predicts that disease rates throughout MENA states will increase from 35.4 million in 2015 to 72.1 million by 2040. Countries with high diabetes prevalence include Kuwait and Saudi Arabia, especially when it comes annual incident rates of Type 1 diabetes in children. Other key triggers, such as obesity and tobacco use, are also increasing, particularly among more affluent and female populations. Consequently, in the upcoming decades, the region's health services are likely to encounter more cases of hypertension, heart problems, and other chronic diseases.

An altogether different concern is the MENA region's high level of HIV infection, which, according to **Harm Reduction International**, has increased by 31 percent since 2001. Of an estimated 240,000 people living with HIV across the region, over

50 percent of new cases are attributable to intravenous drug use. HIV prevalence among users that inject drugs ranges from 0-1 percent in Kuwait and Lebanon to 87 percent in Libya. Access to Opioid Substitution Therapy also varies with only the likes of Iran, Israel, and Morocco offering a credible package of treatment options.

While medicines used to treat diabetes, drug addiction, and other conditions are, in theory, easily accessible, chronic underfunding and patchy health services have hampered efforts to introduce them en masse in the MENA region. Between 2006 and 2011, **MENA countries spent 8.2 percent** of their budgets on healthcare; the global average was approximately 10 percent. There are also obvious disparities, with Gulf Cooperation Council (GCC) states relatively free to spend more on health than conflict-affected Iraq and Syria. For MENA's poorer states the implications are twofold. First, specific healthcare functions must compete for scant government resources. Second, many households face the choice of paying for up to 40 percent of their treatment or foregoing it altogether.

Unhelpful Solutions, Unhelpful Sources

It's hardly surprising then that the MENA region is susceptible to overtures from a highly lucrative trade in counterfeit medicines that fall well below accepted standards of efficacy and quality. The **World Health Organization (WHO) estimates** that approximately 35 percent of the pharmaceutical market in the Middle East could be illicit. If so, then the region is potentially awash with medicines that contain no active pharmaceuticals and harmful additional substances such as rat poison and cartridge ink. The consequences of taking these drugs can be devastating with brain damage and cardiovascular problems among the side effects regularly cited by healthcare professionals.

Fortunately, WHO monitoring for the Eastern Mediterranean region indicates that seizures of counterfeit Diabetes and HIV drugs across MENA remain low. But that's no reason for complacency. In late 2016, two Indian pharmaceutical companies were charged with hiding fake medicines in legitimate commercial transactions. Customers included near-neighbors Bangladesh and Pakistan. Michael Deats, a Group Lead with the WHO's Safety and Vigilance (SAV) Team, also warns of a growing trade in HIV medicines with falsified packaging between Southern Europe and East Africa. This bucks a common trend of sending this counterfeit product to markets in Northern Europe where medicine prices are often higher.

Recent seizures in Saudi Arabia and the United Arab Emirates (UAE) of **erectile dysfunction treatments** and the **painkiller Tramadol** also suggest that manufacturers are increasingly in tune with the 'modern health' concerns of local populations. The same might also be said of **Captagon**, an amphetamine-based stimulant that remains widely available across the MENA region despite being banned since the 1980s. Usage now stretches beyond the nightclubs of the Middle East to Syria's civil war, where all sides use it to remain sharp and focused on the battlefield. Some veterans claim that Captagon makes combatants 'unafraid of anything'and full of 'great courage and power'. A former Free Syrian Army fighter also told the BBC that others would stop providing families with food in order to feed their habit.

Not that any of this will influence the traffickers and suppliers, a nebulous criminal network attracted to the low risks and high rewards offered by counterfeit medicines. Paul Newton, a Professor of Tropical Medicine at the University of Oxford, **attributes this to the relatively weak penalties** for manufacturing and distributing fake drugs compared to those for human and narcotics trafficking. Despite being a worldwide problem, building a global consensus on what exactly constitutes an illegally manufactured counterfeit medicine remains notoriously difficult. Worse still, the United Nations Office on Drugs and Crime (UNODC) warns that the lack of analytical studies on organized criminal groups is undermining efforts to coordinate responses to illicit medicines.

At least governments and international organizations have a better idea of how traffickers saturate the MENA region with fake pharmaceuticals. The journey usually begins somewhere in Asia, with the UNODC labeling China as the **'departure point'** for 60 percent of global counterfeit seizures between 2008 and 2010. Poor regulatory frameworks and oversight also make India a major production hub for fake medicines. To make matters worse, Beijing's and New Delhi's efforts to stem the flow of fake medicines have been offset by the moving of production to other parts of the continent, particularly Southeast Asia.

From Asia, fake pharmaceuticals tend to make their way to consumers via well-established trading routes, including the Internet and, increasingly, the Dark Web, where anonymity and encryption help counterfeiters of all persuasions to hide in plain sight. Circuitous and time-consuming journeys along sea routes are also used, with the UAE's free-trade zones prime locations for the 'sanitizing'of illicit goods. Not surprisingly, traffickers have turned the MENA region's war zones into distribution routes. None more so than Iraq, where conflict, porous borders, and the collapse of regulatory frameworks have facilitated illicit smuggling, sales, and distribution.

Fighting Back

Although the overwhelming majority of MENA states participate in the WHO's Global Surveillance and Monitoring System, it is perhaps unsurprising that the GCC has stolen the march in local efforts to combat fake pharmaceuticals. Not only is it home to some of MENA's largest markets for medical products, member states are also building pharmaceutical industries that they eventually hope will compete with more established manufacturers. One of the best ways to demonstrate that the region has a handle on this sector is to target the influx of counterfeit medicines.

In the build-up to the Second Emirates International Conference on Combating Medicinal Products Counterfeiting, the UAE announced that it is planning to use a device that detects fake medicines within seven seconds. It's possible that this is a Raman mobile spectroscopy instrument which relies on non-destructive tests to identify chemical compounds. In addition, the Emirates are determined to update Federal Law N°4 of 1983 on the pharmaceutical profession and industry by the end of this year. This should result in tighter procedures for seizing suspected shipments and harsher penalties against individuals and companies dealing in counterfeit drugs.

These are the type of initiatives that the UAE hopes will keep its health service free of counterfeit medicines and deter traffickers from using its ports to transport fake products. However, success will also depend on like-minded efforts made elsewhere, particularly in Saudi Arabia and other MENA states. The Kingdom is home to an estimated 3,000-3,500 pharmacies and nearly 200 companies registered under the Saudi Health Ministry. Saudi Arabia also **accounts** for over 60 percent of the GCC market and has recorded over 4,000 patented and generic drugs. Under Saudi Vision 2030, the Kingdom's pharmaceutical sector **is also slated for rapid growth** through foreign investment.

Like the UAE, Saudi Arabia is also looking to advanced technology to assist in the detection of counterfeit medicines entering ports and leaving manufacturing plants. On the policy front, Riyadh hopes to strengthen its bar code regulations by serializing pharmaceutical products by the end of the year. Saudi Arabia is also coordinating its efforts to combat illicit pharmaceuticals with industry giants such as Pfizer. The Kingdom's **Food and Drug Agency** has been conducting market surveys on behalf of such companies, collecting samples from pharmacies and sending them for analysis.

Cooperation with established pharmaceutical companies will also help to allay concerns over Saudi Arabia's close ties with Chinese manufacturers. With the encouragement of Saudi Basic Industries Corp. and Saudi Food and Drug Administration, companies have formed partnerships with Chinese counterparts to enhance grains for large-scale husbandry. Mastering such techniques will enhance the Kingdom's efforts to turn its pharmaceutical industry into a major producer of generic drugs. However, as US Federal Drug Agency operatives will confirm, mixing knowledge and know-how from Chinese manufacturers risks getting closer to fake pharmaceutical products than most companies dare to imagine.

Future's Bright…For Some

No embryonic industry can risk the type of Public Relations fiasco that comes with the distribution and use of counterfeit medicines by health services and humanitarian operations. That's why the likes of Saudi Arabia and UAE have adopted a tech-savvy approach to tracing fake drugs, tighter regulatory frameworks and a careful approach to procurement. The WHO's Michael Deats also praises the GCC's efforts to improve the quality of information it shares with the Global Surveillance and Monitoring System.

Yet there's always room for improvement. Deats highlights the need for more joined-up cooperation between MENA states. Greater coordination and knowledge sharing will only benefit the WHO's monitoring activities and promote a culture of reporting illicit products to regulatory authorities. However, MENA's most fragile states will continue to provide significant obstacles to region-wide efforts to combat counterfeit medicines. These include Egypt, where seizures of fake Hepatitis C treatments are common. Contrasting economic fortunes, scarce government resources, and protracted conflict will ensure that MENA's attempts to tackle counterfeit medicines remain the preserve of its richer and more secure states for the foreseeable future.

*International Policy Digest originally **published this article** on June 1, 2017. Republished at IndraStra.com with authors' permission*

About the Author

Adam Dempsey is an Advisor at Gulf State Analytics (@GulfStateAnalyt), a Washington, DC-based geopolitical risk consultancy.

Dr. Theodore Karasik is the Senior Advisor at Gulf State Analytics.